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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/09/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/755,016

Applicant(s)

Walke et al.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 7, 2002
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) _____ accepted or b) _____ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) _____ approved b) _____ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____

14) The translation of the foreign application is submitted with this communication.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Any questions

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DETAILED ACTION

1. In the **AMENDMENT; AND RESPONSE TO OFFICE ACTION DATED OCTOBER 26, 2001** dated 2/7/2002 (Paper No. 10), Applicants have canceled claims 3 and 4 and amended claims 1 and 2.
2. Claims 1 and 2 are under consideration in this Office Action.
3. All rejections stated in the previous Office Action dated 10/26/01 (Paper No. 8) have been withdrawn. New rejections are stated below in this Office Action.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) of U.S. provisional application number 60/174,686, filed 01/06/2000, is acknowledged.

Nucleotide Sequence and/or Amino Acid Sequence Disclosures

5. The requirements stated in the office communication "NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES" dated 05/21/2002 (Paper No. 11) have been withdrawn. A paper copy of the sequence listing has been received and has been matched with the application.

Claim Rejections - 35 U.S.C. § 101

6. 35 U.S.C. 101 reads as follows:

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant discloses the nucleotide sequence of SEQ ID NO: 3 and the deduced amino acid sequence of SEQ ID NO: 4. Applicants state the protein consisting of SEQ ID NO: 4 is a “novel human protein” (NHP) sharing structural similarity with “trypsin-like serine proteases” which is a generic asserted utility. The specification does not specifically disclose the function/activity of the protein consisting of SEQ ID NO: 4 or its relationship to any disease. The specification does not show any enzyme assays that demonstrate that the protein consisting of SEQ ID NO: 4 has any protease activity. There is no disclosed or “real world” utility associated with the nucleic acid of SEQ ID NO: 3 or the protein of SEQ ID NO: 4. It appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Substantial utility defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utility. Thus, the claimed invention has no specific and substantial asserted utility or a well established utility.

Claims 1 and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1 and 2 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

that a skilled artisan would be able to distinguish the claimed nucleic acids from other materials based on the structural description provided, specifically, the nucleotide sequence of SEQ ID NO. 3, 34 contiguous nucleotides of SEQ ID NO. 3, and the nucleotide sequence that encodes the

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amino acid sequence of SEQ ID NO: 4. The Examiner disagrees for the reasons stated below.

The claims are directed to all possible polynucleotides comprising at least 34 contiguous nucleotide of SEQ ID NO: 3 (claim 1) or all possible polynucleotides encoding any protein comprising SEQ ID NO: 4 which hybridize under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 3 or the complement thereof (claim 2). The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 3 and a polynucleotide encoding a protein consisting of an amino acid sequence of SEQ ID NO: 4.

While there is a structural description provided by the specification, specifically, the nucleotide sequence of SEQ ID NO: 3, 34 contiguous nucleotides of SEQ ID NO: 3, and the nucleotide sequence that encodes the amino acid sequence of SEQ ID NO: 4, there is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structure to function/activity relationship, other than the claimed polynucleotide comprises at least 34 contiguous nucleotide of SEQ ID NO: 3 or the polynucleotide encodes any protein comprising SEQ ID NO: 4, for which no predictability of structure to function/activity relationship is apparent.

Furthermore, the specification does not provide a written description of the nucleotide sequence that is 5' or 3' of SEQ ID NO: 3, 34 contiguous nucleotides of SEQ ID NO: 3, or a nucleic acid encoding SEQ ID NO: 4. The specification does not provide a written description of the N-terminal or C-terminal amino acid sequence of the amino acid sequence of SEQ ID NO: 4. Given this lack of additional representative species as encompassed by the claims and any structure to function/activity relationship, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention

entire

In claim 2, the phrase "hybridizes under highly stringent condition" renders the claim vague and indefinite because the specific "highly stringent" hybridization and washing conditions

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are not recited in the claim and the specification does not clearly define the "highly stringent" hybridization conditions.

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al. (Accession AA884376).

Strausberg et al. (Accession AA884376) teach a nucleic acid molecule which comprises 48 contiguous nucleotides of SEQ ID NO: 3 (see enclosed alignment). Thus, the reference teachings anticipate the claimed invention.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

Patent Examiner
Technology Center 1600
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